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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,248	02/13/2001	Robert Amson	065691/0209	2805
23533	7590	02/04/2004	EXAMINER	
STEPHEN B MAEBIUS FOLEY AND LARDNER 3000 K STREET N W SUITE 500 WASHINGTON, DC 20007-5109			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/762,248	<b>Applicant(s)</b> AMSON ET AL.	
	<b>Examiner</b> J. Douglas Schultz	<b>Art Unit</b> 1635	

-- Th MAILING DATE of this communication app ars on th cover sheet with the correspondenc address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 13, 14 and 17-21 is/are rejected.
- 7) ☒ Claim(s) 12 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

**DETAILED ACTION**

***Prosecution re-opened***

1. The previously indicated allowability of claims 11, 13, 17 and 18 is withdrawn in view of the rejection set forth below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

3. Claims 11, 13, 14, and 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims of the above invention are drawn to a method for identifying compounds with anti-anxiety or long term memory restoring activity comprising administering a test compound to an animal comprising at least one non- functional allele of the p53 gene, and determining whether said test compound decreases anxiety or long term memory storage in said animal.

The specification teaches a method of testing for compounds having anxiety-reducing or memory-restoring activity in a mouse. The specification does not teach any other animals in which the claimed method might be used. Furthermore, the specification does not appear to suggest in any way that the claimed methods were ever contemplated as working in any other animal besides mice. Accordingly, the specification is not considered to support claims to

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methods of identifying anti-anxiety compounds or methods of identifying compounds that reduce memory storage.

4. Claims 11, 13, 14, and 17-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of identifying compounds with anti-anxiety activity or memory restoring activity in mice, does not reasonably provide enablement for methods of identifying compounds with anti-anxiety activity or that improve deficiency in long term memory storage in any other animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection is repeated for the same reasons of record as set forth in the Office action mailed April 8, 2003, but is amended to emphasize the elements necessitating this rejection, and to include claims previously indicated as allowable.

The factors listed below have been considered in the analysis of enablement:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The claimed invention is drawn to methods of identifying compounds that have anti-anxiety activity or that improve deficiency in long term memory storage in any animal that is heterozygous or homozygous for a non-functional allele of p53.

The specification teaches that p53 deficient mice have elevated levels of anxiety and memory deficiencies. The specification also teaches that such screening methods utilizing p53 deficient mice are novel, and that the inventors are the first to show that a p53 deficiency in mice leads to a higher level of anxiety and a decrease in long term memory storage. At issue here is whether the method will work in the genus of *any animal* as broadly claimed by applicant.

The state of the prior art suggests that applicants are correct in asserting the novelty of the finding that p53 deficient mice display higher levels of anxiety and decreased long-term memory storage. Furthermore, the combination of the related prior art along with the amount of direction provided by applicants in their working examples in mice is considered to provide one of ordinary skill with the knowledge necessary to practice the screening methods in mice as disclosed by applicants. However, p53 is widely expressed in many species, and the prior art further demonstrates that these p53 functions vary from species to species, leading to substantial unpredictability in trying to practice such methods in any species other than mice as disclosed.

For example, Resnick et al. (Proc. Nat'l. Acad. Sci. 2003. 100(17)9934-9939) teach that there are likely to be hundreds of genes regulated by p53, and that these genes are involved in function as diverse as apoptosis, growth arrest, DNA repair, and checkpoint responses (page 9935, left column). Resnick further teach that certain p53-regulated genes in humans are different from the p53-regulated genes of mice (page 9938, first paragraph). Wadhwa et al. (J. Biol. Chem. 2002. 277(39) 36665-36670) also teach that p53 is regulated differently in humans as compared to mice. Accordingly, because the genes that regulate and are regulated by p53 differ across mice and humans, and because these differences would thus lead to different phenotypes, one could not predict whether an animal would exhibit a p53-related increase in

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anxiety or decrease in memory storage solely based on what is observed in the mouse. This unpredictability would necessarily cause one of skill in the art to engage in trial and error experimentation to determine if p53 related deficiencies lead to increased anxiety and decreased memory storage, as required to practice applicant's invention over the claimed scope.

*Allowable Subject Matter*

5. Claims 12 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

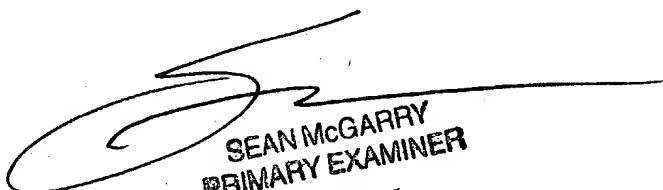
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James Douglas Schultz, PhD

  
SEAN MCGARRY  
PRIMARY EXAMINER  
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